REMARKS

With entry of this amendment, the claims pending for consideration are claims 1-11,13-17, 19, 23-36, 38-42, 44, 48-55, 59-61 and 67-77 as amended, and newly added claims 83-89. Claims 12, 37, 56, 57 and 78-82 are cancelled by this amendment. The subject matter of former claims 56, 57 and 78-82 is currently presented in newly added independent claims 83-89. Claims 23-25 are allowed.

Reconsideration of the application, as amended, is respectfully requested.

Double Patenting Rejection

Claims 1, 19, 26 and 44 are again, and claims 67-76 are newly, provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of copending, commonly owned, later filed, USSN 10/041,363. Applicants previously requested that the rejection be held in abeyance inasmuch as neither case currently contains any allowed claims. The PTO maintained the rejection and stated at page 5 of the Office Action: "No allowable material can be indicated when a ground of rejections remains." Applicants do not understand the PTO's response.

By requesting that the rejection be held in abeyance, applicants were not arguing the rejection, just "putting it on the back-burner" until there was an indication of otherwise allowable subject matter. Moreover, the PTO's statement quoted above does not seem to be consistent with MPEP, Section 804 I., B and C. Specifically, in

subsection B, page 800-19, the MPEP indicates that where the provisional double patenting rejection is the only rejection remaining in an application, then the examiner should withdraw the rejection and permit the application to issue as a patent, thereby converting the provisional double patenting rejection in the other application into a double patent rejection. Consistent with MPEP Section 804, applicant will consider the propriety of a terminal disclaimer in either the instant application or USSN 10/041,363, depending on which application issues first and depending on the claims that may ultimately be allowed in these applications. Applicants cannot properly be requested to do more at this time in view of the unresolved status of these cases.

The Section 112 Rejections

Claims 12, 15, 37, 40, 48-50, 52-55, 60, 61 and 71-77 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. In response to the various Section 112 rejections, applicants amended claims 15, 40, 48, 52, 54, 60, 61, 71-77 as provided above. Claims 12 and 37 were cancelled inasmuch as the claims from which they depend cover the erythropoietin glycoprotein product regardless of how such glycoprotein is made. The currently pending claims are not dependent on any process of manufacture of the glycoprotein. Claims 3, 28 and 34 were amended to correct spelling errors. Claims 53 and 55 were amended to delete extra punctuation.

The above amendments are fully supported by the specification and are not believed to introduce any new subject matter.

Applicants submit the foregoing amendments overcome the pending Section 112 rejections and request withdrawal of these rejections.

The Section 102 Rejections

Claims 1-4, 6, 7, 9-12, 26-29, 31, 32, 34-37 and 54 are again rejected under 35 USC § 102 (b) as being anticipated by U.S. Patent No. 4,992,419 (Woog et al.). This rejection is traversed.

Applicant maintains the arguments presented in April 15, 2003 amendment that Woog does not disclose applicant's aqueous EPO compositions that are storage stable at room temperature. To make his compositions storage stable, that is provide a shelf-life, at room temperature, Woog lyophilized them. Contrary to the PTO's asserted expectation at page 7 of the Office Action of the stability of the Woog formulations, Woog himself states that his reconstituted aqueous formulations are only stable at room temperature for a few months. *See, e.g.*, column 4, lines 3-8. Such a short shelf-life is not commercially desirable. Thus, Woog's compositions cannot be the same as applicant's compositions.

At the top of page 7 of the Office Action, the Patent office provides certain references to Woog wherein the PTO picks and chooses various components of the Woog formulations and equates each of these components to applicant's formulations. This approach by the PTO is legally inappropriate and moreover, technically incorrect. Woog is not even a proper 102 reference. The various components attributed to Woog on page 7 of the Office Action do not accurately reflect the Woog formulations. The Woog formulations always contain urea. Moreover, as mentioned above, Woog himself states at column 4 that the storage stability of his liquid compositions is limited to "a few months at ambient temperature." Column 4, line 8. Thus, clearly, the Woog

formulations are different from those disclosed by applicant inasmuch as applicant's formulations are stable are room temperature for at least about six months (see, e.g. Table 3, page 46, of applicant's specification.)

While applicant submits that Woog is not a proper 102 reference at all, applicant has amended claims 1 and 26 to state that the claimed liquid compositions are stable at room temperature for at least about six months and do not contain urea. This amendment is fully supported by applicant's specification, for example in Example 10 and Table 3, page 46, and page 2. Applicant submits the claims as amended are fully patentable over Woog and that this rejection is overcome.

Analogously, claims 1-9, 11 and 12 are also again rejected as being anticipated by WO 96/40073 (Zale et al.). This rejection is also traversed.

Applicant maintains the arguments presented in April 15, 2003 amendment that Zale is completely inapposite. Zale relates to a sustained release composition wherein particles of aggregation-stabilized, biologically active, EPO are dispersed in a polymeric matrix of a biocompatible polymer. See, e.g., page 2, lines 9-16. The anti-aggregation agent described in Zale (e.g., at page 5, lines 30 – page 6, lines 28, cited by the Examiner) has an effect which is totally inconsistent with applicants' formulations; that is, the Zale aggregation agent reduces the EPO solubility by precipitating the EPO from the aqueous solution. In contrast, applicant's formulations retain biologically active, solubilized, non-precipitated EPO stable for several months at room temperature. See applicants' specification at paragraph 4 and Table 3.

The PTO maintained its rejection because the limitation of "solubilized, non-precipitated EPO" is not contained in applicant's claims. Applicant respectfully disagrees. Applicant's claims and specification clearly state that applicant's compositions are liquid in the form of an aqueous solution comprising an EPO glycoprotein. It is respectfully submitted that one would not have an aqueous solution if the components of said solution were not solubilized. To require applicant to add the term "solubilized" to the claims would add a redundancy that can only lead to confusion.

Similarly, with respect to the term "non-precipitated," this term too would be redundant in applicant's claims. Applicant's claims are directed to a stable liquid composition containing EPO. One skilled in the art would understand, and applicant specifically states at page 2, that "unstable" in this art means degradation of the protein. Thus, by stating that applicant's EPO-containing compositions are stable at room temperature, applicant is already saying that the EPO glycoprotein product is not degraded, which includes precipitation.

Applicant should not be required to add terms to claims which merely add a redundancy to the claims. The rejection over Zale is improper and should be withdrawn.

Claims 1-17, 19, 26-42, 44, 51, 59 and 67-70 are newly rejected as being anticipated by U.S. Pat. No. 6,583,272 B1 (Bailon). This rejection is overcome.

The EPO glycoprotein product-containing formulations disclosed in Bailon are the work of the inventor of the instant application. Attached is a Rule 132 Declaration by inventor Dr. Papadimitriou attesting to the fact that he is the inventor of the

formulations disclosed but not claimed in the Bailon patent. This rejection is thus overcome.

In view of the above arguments and amendments, the Section 102 rejections are overcome in part and traversed in part and should be withdrawn.

The Section 103 Rejections

Claims 1-4, 6, 7, 9-13, 26-29, 31, 32, 34-38 and 54 are rejected under 35 USC § 103(a) as being obvious over Woog, supra, in view of WO 92/06116 (Rosen et al.). This rejection is again traversed.

For the reasons stated above, and in view of applicant's arguments presented in April 15, 2003 amendment, applicant submits that Woog does not teach or fairly suggest a liquid erythropoietin glycoprotein–containing composition that is storage stable at room temperature for at least about six months and does not contain urea. Rosen's disclosure of the amino acid sequence of recombinant human EPO does not make up for the deficiencies of the primary reference, Woog. Woog, alone or in conjunction with Rosen, does not fairly disclose applicants' specific liquid erythropoietin-containing compositions that are stable at room temperature, for up to about six months, without the use of serum albumin as an additive. See, e.g., the instant application at paragraphs 4, 8, and Table 3.

In addition, claims 1-4, 6, 7, 9-12, 14-17, 26-29, 31, 32, 34-37, 39-42 and 54 are again rejected under 35 USC § 103(a) as being obvious over Woog in view of EP 0640619 (Elliot). This rejection is also traversed.

Elliot is cited for disclosing EPO analogs having at least one additional glycosylation site. For the reasons provided above, Woog does not teach or fairly suggest applicants' claimed liquid erythropoietin glycoprotein-containing composition that are stable at room temperature for at least about six months. Thus, regardless of whether the EPO is unmodified or modified, the EPO formulations of Woog are not suggested to be liquid compositions that are storage stable at room temperature for at least six months.

The Section 103 rejections are also overcome and should be withdrawn.

Claims 56, 57 and 78-82 are objected to as being dependent from a rejected base claim but are indicated to be allowable if rewritten in independent form. Applicant has rewritten these claims as newly added independent claims 83-89 that include those limitations that were present in the base claims from which these claims depend before any amendments that were made to the base claims by the current amendment. For example, former claim 56 is now presented as new claim 83 and it includes all the limitations of base claim 26 except for the phrase "for at least six months and not containing urea" inasmuch as former claim 56 was indicated to be allowable even without such phrase.

Conclusion

In view of the above amendments and the foregoing remarks, and the concurrently submitted Rule 132 Declaration of Dr. Papadimitriou, it is respectfully submitted that the instant application is in condition for allowance and prompt allowance of the application is solicited.

Respectfully submitted,

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